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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

MARVIN H. A.

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/220,142

Applicant(s)

Friend et al.

Examiner

Ardin Marschel

Art Unit

1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 5/22/01 and 7/30/01

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1, 3-50, 58-64, 72-78, 89-100, and 105-124 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1, 3-50, 58-64, 72-78, 89-100, and 105-124 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Interview Summary (PTO-413) Paper No.'s: _____

17) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

18) ☐ Notice of Informal Patent Application (PTO-152)

19) ☒ Information Disclosure Statement(s) (PTO-1449) attached sheet

20) ☒ Other attachment for PTO-948

Applicants' arguments, filed 5/22/01 and 7/30/01, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicant is hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". It is noted that a PTO Form 948 was mailed with Paper No. 4 on 8/9/99. Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Claims 14, 22, 47, 61, 92, and 119 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is noted that the enabling discussion of the operation of hclust is incorporated by reference to a software package in the

specification on page 24, lines 15-16. This algorithm is essential subject matter for the practice of the above listed claims and as such cannot be enabled by incorporation by reference to a printed publication. See the following paragraph regarding improper incorporation by reference for essential subject matter.

The incorporation of essential material by reference to a foreign application or foreign patent or to a publication inserted in the specification is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or applicant's attorney or agent, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. *In re Hawkins*, 486 F.2d 569, 179 USPQ 157; *In re Hawkins*, 486 F.2d 579, 179 USPQ 163; *In re Hawkins*, 486 F.2d 577, 179 USPQ 167.

Claims 18, 26, 50, 64, 96, 106, and 123 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18 etc. are vague and indefinite regarding step (a) therein. In claim 18 a fractional improvement is determined but confusingly without indicating what is performed in order to obtain an improvement. It is noted that steps (b)-(d) in claim 18 cites steps for obtaining some type of improvement. It seems that step (a) summarizes what is performed in steps (b)-(d) with the repeating step (e) but does not indicate what is an actual

improvement versus the improvements in steps (b)-(d) with the repeating of step (e). This is also an unclarity in the remainder of the above listed instant claims. Clarification via clearer claim wording is requested.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1, 3-8, 10-13, 15-17, 19-21, 23-25, 27-46, 48, 49, 56-60, 62, 63, 72-76, 89-91, 93-95, 97-100, 105, 107-113, 115-118, 120-122, and 124 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Eisen et al. [PNAS 95:14663(1998) and (already of record)].

It is firstly noted that Eisen et al. was publicly available prior to the instant application filed date via its December 6,

1998, date on the cover of the publication as well as a date of receipt at the PTO on December 10, 1998. The abstract and title of Eisen et al. describes the cluster analysis and display of genome-wide expression data as indications of the status of cellular processes. The cluster analysis of thousands or tens of thousands of gene expression patterns for various purposes is described in the introductory paragraphs on page 14863. Included in this introduction is the following of drug treatment in individuals as well as finding drug targets. On page 14863, second column, first full paragraph, the description of supervised clustering is discussed in reference to "known reference vectors" which is discussed as being derived from known conditions such as defining expression clusters first via unsupervised clustering to find patterns of expression followed by supervised clustering. In the remainder of the reference various cluster methods are discussed such as the similarity metric or hierarchical clustering on page 14864. These descriptions are interpreted as the compilation of cell constituent profiles, especially directed to gene expression profiles, clustering them into groups of co-varying or co-regulated genes via various unsupervised or supervised clustering techniques as discussed above in order to determine drug effects or perturbations as instantly claimed. The usage of supervised clustering in the reference as a known reference vector is

reasonably interpreted as the projected profiles of instant claim 29, for example, when further utilized in subsequent analyses as suggested in the reference. It is noted that the field of what is suggested to be analyzed is unlimited in the reference and suggestive of a multitude of possibilities for drugs, for example, via the generic citation of drug treatment or drug target practice on said page 14863. It is noted that the broad concept of drug treatment or targets is well known to anyone in such a field to include a huge number of possibilities and supports the concept of analyzing many more than 5, 10, etc. profiles for such analyses. Alternatively, the analysis of a large number of profiles is suggested in Figure 1-3 in the reference in which arbitrary large numbers of profiles are analyzed for each set of gene cellular constituents.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to perform the genome-scale expression analysis of the reference with the clustering of data in order to determine those sets of genes which are affected as to expression by various conditions generically for various analyses, one species of which is suggested as drug target or drug treatment analysis thus resulting in the practice of the instant invention.

Claims 1, 3-13, 15-17, 19-21, 23-25, 27-46, 48, 49, 58-60, 62, 63, 72-78, 89-91, 93-95, 97-100, 105, 107-118, 120-122, and

124 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Eisen et al. [PNAS 95:14863 (1998) and (already of record)], taken in view of Welsh (P/N 5,686,114).

Eisen et al. has been summarized above but does not indicate that drug toxicity should also be studied as to such effects of drug treatment.

Welsh in column 5, lines 27-29, suggests and motivates the issue of the study of drug toxicity along with dosing or treatment in drug targeting as also indicated as important to study in instant claims such as claim 9 etc. Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to also profile drug toxicity along with efficacy in evaluating profiles of drug perturbations as instantly claimed.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4026.

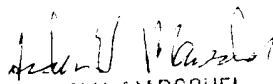
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Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

October 5, 2001


ARDIN H. MARSCHEL
PRIMARY EXAMINER